K061721

510(k) Summary

Submitter's name:	Emergency Products and Research
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Contact Person	Mark Moehler
Summary Prepared	June 13, 2006

Trade Name: Pedi-Spider Strap
Common Name: Pediatric Backboard Strap
Classification Name: Restraint
Equivalent Product: Pedo Cush Pedo Cuddle

The Pedi-Spider is equivalent to the Pedo Cush because the main use of the device is to immobilize the pediatric patient. The Pedi-Spider does this on a backboard whereas the Pedo Cush does it in a dentist chair. The physical characteristics are very similar, in that they both use Velcro to hold the pediatric patient in place and keep them from injuring themselves further and to minimize the trauma for the situation. The Pedo Cush utilizes material and Velcro and the Pedi-Spider utilizes 1 ½" nylon or polypropylene material in a cargo net fashion with Velcro on the ends for securing the strap to the backboard.

The intended use of the Pedi-Spider is to secure an injured child to a backboard at the scene of an emergency and during the transport phase of treatment. The device should be applied and tightened enough to secure the patient from movement, but not tight enough that would restrict breathing or circulation. Two fingers should be able to be placed under the straps lying flat to the chest and under the strap.

Indications for Use
510(k) Number K061721

Device Name Pedi-Spider Strap

Indications for Use: The Pedi-Spider strap is designed for securing a pediatric patient to a long spine board, by the use of a checker board series of straps that are placed over the patient and secure to the back board with Velcro hook and loop closures on each side of the back board. The device should be used on children from 10 to 100 pounds and 12 to 55 inches in height.

Prescription Use__XX____ AND/OR Over-the-Counter Use____

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF cdrh, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2006

Mr. Mark Moehler
Emergency Products and Research
890 West Main Street
Kent, Ohio 44240

Re: K061721
Trade/Device Name: Pedi-Spider Strap
Regulation Number: 21 CFR 880.6900
Regulation Name: Hand-Carried Stretcher
Regulatory Class: I
Product Code: NZD
Dated: July 24, 2006
Received: July 27, 2006

Dear Mr. Moehler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K061721

Device Name Pedi-Spider Strap

Indications For Use: The Pedi-Spider strap is designed for securing a pediatric patient to a long spine board. This would be used in the event of an injury, or suspected injury to the spinal area of a pediatric patient. The purpose of this device is to immobilize the patient while being stabilized at the scene of an emergency and during the transport of the patient to a treating medical facility. The device works by having a series of straps that are placed over the body of the patient and secured to the sides of the backboard with loop and hook closures. This series of straps are connected on each side and in the middle of the device to provide stability and extra rigidity.

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 SubpartC)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
...on Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061721